

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

BAYER HEALTHCARE
PHARMACEUTICALS INC. and DOW
PHARMACEUTICAL SCIENCES, INC.

Plaintiffs,

v.

RIVER'S EDGE PHARMACEUTICALS,
LLC; TERESINA HOLDINGS, LLC;
MEDICAL PRODUCTS LABORATORIES,
INC.; and STAYMA CONSULTING
SERVICES, LLC

Defendants.

Case No. 11-cv-01634-RLV

**PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR LEAVE
TO FILE SUPPLEMENTAL BRIEFS AND PRECLUDE EVIDENCE OF
SECONDARY CONSIDERATIONS**

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Plaintiffs Bayer HealthCare Pharmaceuticals Inc. (“Bayer”) and Dow Pharmaceutical Sciences, Inc. (“Dow”, and collectively, “Plaintiffs”) submit this Opposition To Defendants’ Motion For Leave To File Supplemental Briefs And Preclude Evidence Of Secondary Considerations (the “Motion”).

I. INTRODUCTION

Defendants’ Motion is *not* about the need to remedy purported prejudice resulting from highly confidential third-party technical information produced for the first time in February 2014. Instead, the Motion marks the culmination of Defendants’ agenda over the last six months to use a manufactured discovery dispute as an excuse to reopen claim construction and reorient Defendants’ case. Indeed, Defendants devote almost no effort to explaining how any of the newly-produced information has any bearing on the Motion -- nor can they. Instead, Defendants rewrite the history of the last two years -- including their ad hominem attacks on Plaintiffs and their counsel -- hoping to convince the Court to reboot the case so that Defendants’ new counsel can revise their key contentions and case theories. There is simply no basis, however, to restart the case at this point, and doing so would reward Defendants for their gamesmanship.

Defendants’ Motion follows their “Emergency Motion” to postpone the trial, in which Defendants represented to the Court that they wanted to narrow the issues

for trial to conserve party resources. (D.I. 283 at 6-8.) Since the Court granted Defendants' Emergency Motion, however, it has become clear that Defendants filed their Emergency Motion, their motion to compel production of the *Medicis* documents (D.I. 235), and now this Motion all in furtherance of one goal: to push back trial so Defendants can revise their claim constructions and case strategies.

Defendants' agenda is further confirmed by events prior to the instant "dispute." Immediately after the introduction of Defendants' new counsel, Defendants attempted to use their expert reports to change their proposed constructions of disputed claim terms and to add invalidity contentions that were never before disclosed in this case. These new and untimely arguments are the subject of Plaintiffs' January 16, 2014 motion to strike. (D.I. 261.) After Plaintiffs filed that motion to strike -- endangering the success of Defendants' agenda -- Defendants turned to the pretext of the *Medicis* documents as a last resort.

As the record surrounding the *Medicis* documents confirms, however, there is simply no basis to reopen claim construction, fact discovery or expert discovery. Defendants had all of the relevant and material information from the *Medicis* case in April 2013, including the deposition transcripts of the inventors. The current Motion amounts to little more than Defendants arguing: "Well, if we are given a second chance, we will use that information this time around in additional claim

construction and discovery.” There are no grounds to give Defendants a second bite at the apple.

Ironically, Defendants’ attempt to reorient their case would not have been possible *at all* had it not been for their earlier actions in withholding significant discovery from Plaintiffs, including undisclosed assignees of the ANDA and an updated but undisclosed ANDA. Those actions led the Court to reset case deadlines, extend discovery by six months and extend the regulatory stay in this case by seven months. (D.I. 138, 167; *see also* D.I. 168.) There is no doubt that this case would have been already tried and a decision issued had it not been for Defendants’ actions at that time. Defendants should not be rewarded for delaying the case twice, by being permitted to use the current delay as an opportunity to amend their case positions.

Setting aside Defendants’ transparent and inappropriate motives, the factual predicates behind their Motion are equally unavailing. Defendants’ recent filings are all based on the allegation that plaintiff Dow argued a proposed construction of the “lightly cross-linked” term in the *Medicis* case that is somehow inconsistent with Bayer’s proposed construction in this case. Defendants are now forced to admit, however, that “*the Medicis Plaintiffs did not propose a construction for ‘lightly cross-linked polyacrylic acid polymer’ even though it was a disputed term*

in the case.” (Motion at 10, n. 6.) Because neither *Medicis* nor Dow submitted a proposed construction of the term “lightly cross-linked” in the *Medicis* case, there is no basis to argue that Plaintiffs in this case are taking an inconsistent position with regard to claim construction.

Defendants’ Motion should also be denied because of the flawed factual assertions that underpin the requested relief. Here are the facts:¹

- First, Defendants had the material information from the *Medicis* case at least as early as April 2013; the unredacted *Medicis* documents do not include any new information that warrants renewed claim construction and summary judgment briefing;
- Second, Defendants suffered no prejudice from the disclosure of the inventor testimony from the *Medicis* case in April 2013; and
- Third, Defendants suffered no prejudice from the timing of Plaintiffs’ interrogatory responses concerning secondary considerations of nonobviousness. Most telling about Defendants’ real motives in filing their Motion was their complete disinterest in obtaining testimony on this issue during fact discovery. In fact, Defendants sought no fact or Rule 30(b)(6) deposition testimony on the issue of secondary considerations *at all*.

¹ Consistent with recent practice, Defendants’ brief is saturated with factual inaccuracies, misquotes and mischaracterizations of the record and unfounded exaggeration. In an effort to focus the dispute, Plaintiffs have not taken on herein every inaccuracy and, instead, have endeavored to address only those issues that impact the relief requested and which are directed to the scheduling and management of the case. Plaintiffs are available to address any issues concerning Defendants’ Motion during oral argument if the Court so desires.

Rather than relying on the record, Defendants merely regurgitate the same discredited accusations that they made in their motion to compel -- each of which Plaintiffs already rebutted with cited evidence. Plaintiffs, therefore, hereby incorporate by reference their opposition to that motion (D. I. 351) in the interests of efficiency.

Defendants' Motion also reflects a pattern of behavior in their filings that has become increasingly and disappointingly routine. Rather than debate the facts, arguments or the law, Defendants' strategy is to demonize Plaintiffs and their counsel by falsely accusing them of serious charges of willfully withholding responsive documents, all based on manufactured facts and half-truths. Plaintiffs' counsel has no choice but to take these allegations seriously, but does not believe that such accusations should be brought against members of the bar without hard proof and careful deliberation. Defendants' Motion (as well as their recent motion to compel) lacked both.

Defendants' Motion should, accordingly, be denied.²

² Defendants' Motion blends together the question of sanctions, which is currently pending before the Court based on Defendants' motion to compel (D.I. 235), and the question of the propriety for additional discovery and/or motion practice. Rather than reargue the sanctions issues, Plaintiffs incorporate by reference their arguments in Plaintiffs' Opposition to the Award of Attorneys' Fees and Expenses Under Rule 37, Fed. R. Civ. P. (D.I. 351), as if fully stated herein.

II. ARGUMENT

A. Defendants Cannot Justify Revising Their Claim Construction And Summary Judgment Arguments At This Late Date

1. There Is Nothing New In The Unredacted *Medicis* Documents That Impacts Claim Construction

The purported basis for Defendants’ sudden need to “supplement” claim construction is the production of unredacted documents from the *Medicis* litigation. That justification, however, is belied by Defendants’ failure to demonstrate how *any* of those “new” documents contain any information that is actually new, relevant or unique. All of the documents that could have been relevant to Defendants’ case were produced in April of 2013.³

The record confirms this fact: more than *two months* after producing unredacted documents from the *Medicis* litigation, Defendants have still failed to show how they could be prejudiced by the timing of that production. As Plaintiffs have explained in multiple prior filings with the Court, Defendants either had the allegedly “new” information in April 2013 (and disregarded it), or the “new” documents are not relevant to any issue in this case. (D.I. 240, 327, 351.)

³ The fact that Defendants’ Motion is truly directed to claim construction is evident from their filing. Although they seek to supplement their summary judgment briefing, Defendants provide no argument or support for that request.

Each of Defendants' attempts to argue prejudice to their case has failed:

- Defendants argued on February 24, 2014 that the expert report of Dr. Marcus Weck from the *Medicis* case was new, of vital importance and previously withheld. (D.I. 299.) To the contrary, however, that expert report was provided to Defendants on April 4, 2013 -- and Defendants did not use that report during fact or expert discovery. Moreover, that report -- which was submitted *after* the *Medicis* court rendered its claim construction decision -- offered infringement opinions concerning the proposed generic version of Medicis' Ziana[®] product, which have no relevance to *this* case concerning Defendants' proposed generic Desonate[®]. (D.I. 327.)
- Defendants argued that Plaintiffs intentionally withheld the opinions of Dr. Charles Daniels -- an expert for Actavis. (D.I. 317 at 8.) Defendants omitted the key fact that Plaintiffs provided Defendants with Dr. Daniels' expert report in April 2013. Defendants also argued that during his deposition, Dr. Daniels offered opinions that undermine Plaintiffs' proposed construction of "lightly cross-linked". (D.I. 317 at 8.) The facts prove otherwise. During his deposition, Dr. Daniels was presented with the claim construction declaration of Dr. Christopher Bowman, Bayer's *Markman* declarant in this case. ***Dr. Daniels agreed with that declaration.*** (D.I. 327 at 8-9.) There is, accordingly, no conflict here and no prejudice to Defendants. Defendants' argument that this "deposition would have been critical to Defendants' fact and expert discovery" is simply not credible. (Motion at 11.)
- At the hearing on their Motion, Defendants emphasized repeatedly the transcript of Dr. Joel Zatz, which had not been previously relied upon by Defendants for any reason. (*See, e.g.*, D.I. 333 at 13.) Defendants argued that Dr. Zatz offered positions on claim construction that were different from Plaintiffs' positions in this case. That is incorrect. Dr. Zatz testified *after* claim construction proceedings were complete in the *Medicis* case and *after* the Magistrate Judge in that case issued his public Report and Recommendation. (D.I. 338.) By that point, the *Medicis* court had already construed the claim term "lightly cross-

linked polyacrylic acid polymer.” (D.I. 351-3.) Moreover, the cropped portion of testimony relied upon by Defendants during the hearing concerned Dr. Zatz’s application of the *Medicis* court’s construction.

Beyond that, it is unclear why documents from the *Medicis* case would be relevant to claim construction at all. It is axiomatic that the Court’s focus must “begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter which the patentee regards as his invention.” *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1370 (Fed. Cir. 2005). The record is undisputed that Defendants already had the documents relevant to claim construction at the time the parties filed their briefs in 2012. Indeed, Defendants attached the *Medicis* plaintiffs’ claim construction brief to their *Markman* briefing in this case. (D.I. 122-4.) They never used that brief in depositions taken in this case.

Moreover, Defendants have insisted in filings with this Court that their claim constructions have been (and would presumably remain) consistent throughout this litigation. (*See, e.g.*, D.I. 268 at 6-10.) Defendants have no basis, therefore, to change their claim constructions now, on which Plaintiffs have based their case strategies for almost two years. (*See* D.I. 104.)

2. Defendants Mischaracterize Inventor Testimony -- Which They Have Had Since April 2013 And Which Is, At Any Rate, Generally Irrelevant To Claim Construction

The inventor deposition transcripts from the *Medicis* case were produced to Defendants in this case in April 2013, long before the close of discovery and the production of unredacted documents in February 2014. On October 21, 2013, Defendants' counsel sent a letter to Plaintiffs seeking to reopen claim construction based on that production. (Ex. 1 at 1.)⁴ Defendants, however, never followed up on that request. The only logical conclusion that can be drawn is that Defendants carefully deliberated and decided *more than six months ago* that the inventor transcripts did not warrant supplementing or revising claim construction. Defendants did not care about those transcripts until February 2014, after Plaintiffs filed their motion to strike, when the transcripts became part of the contrivance under which Defendants brought their motion to compel.

Beyond that -- and as they did in their motion for summary judgment and their "Emergency Motion" to postpone trial -- Defendants cite in their Motion out-of-context excerpts from Dr. Gordon Dow's deposition testimony in the *Medicis*

⁴ As used herein, "Ex." refers to the exhibits attached to the contemporaneously-filed Declaration Of Diana G. Santos, Esq., In Support Of Plaintiffs' Opposition To Defendants' Motion For Leave To File Supplemental Briefs And Preclude Evidence Of Secondary Considerations. All emphasis in this brief is added unless otherwise noted.

litigation, which involved different asserted patent claims and an accused product not at issue in this case. (D.I. 257-1 at 3-4, 22, 22; D.I. 283 at 3-4.) In his deposition in *this* case, however, Defendants presented Dr. Dow with his testimony from the *Medicis* case and Dr. Dow explained why Defendants' arguments concerning his testimony are wrong. (Ex. 2 at 46:6-48:3; 52:5-53:5; 53:12-55:20; *see also* D.I. 298 at 19-20, n.7; D.I. 279 at 12-13.) Defendants' insistence on ignoring the record and arguing incomplete facts -- despite Plaintiffs' repeated corrections -- belies Defendants' stated motives behind their Motion.⁵

Dr. Dow's testimony from the *Medicis* case, regardless of its content, cannot form a basis to reopen claim construction here. This is because when it comes to claim construction -- as Plaintiffs' presented to the Court during oral argument on Defendants' motion to compel -- Dr. Dow's testimony is largely irrelevant as a matter of law. (D.I. 329 at 88.) The Northern District of Georgia has noted the Federal Circuit's instruction that "the testimony of [the inventor] and his patent attorney on the proper construction of the claims is entitled to no deference."

Furukawa Elec. North Am., Inc. v. Sterlite Optical Techs., Ltd., No. 02-2149, 2006 WL 6254103, at *4 (N.D. Ga. Jan. 18, 2006) (quoting *Markman v. Westview*

⁵ Defendants also omit from their Motion the fact that they initially declined to take Dr. Dow's deposition in this case, and only changed their minds in July 2013 (D.I. 185), after fact discovery was extended by the Court due to Defendants' discovery misconduct.

Instruments, 52 F.3d 967, 983 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996)); *see also Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997) (The “testimony of an inventor and his attorney concerning claim construction is [] entitled to little or no consideration.”).

At oral argument, the Court recognized the limited import of inventor testimony:

The Court: [...] But it is evidence and I understand, but this is not like summary judgment, you don’t hand this up and get summary judgment.

Mr. Hall: I believe in Markman you do.

The Court: Okay, well.

Mr. Hall: For the *Markman* hearing, if their expert has taken the position --

The Court: But this is not their expert in this case.

(D.I. 329 at 58.)

There is simply no basis to reopen claim construction based on Dr. Dow’s deposition testimony in the *Medicis* case.

B. Plaintiffs Will Be Substantially Prejudiced If Defendants Are Allowed To Re-Brief Claim Construction and Summary Judgment

Defendants’ experts offered untimely, new claim construction and invalidity contentions in this case in violation of the Court’s Scheduling Order, which is the

subject of Plaintiffs' motion to strike. (*See* D.I. 261-1 at 8 (citing D.I. 263-1, 263-2, 263-3).) It would be unjust to reward Defendants for violating the Scheduling Order by permitting them to supplement their claim constructions now, based on a manufactured discovery dispute that has *no* relationship to claim construction.

The prejudice to Plaintiffs would be particularly severe where, as here, Plaintiffs based their case strategies on the claim constructions that Defendants first disclosed almost two years ago pursuant to the Court's Patent Local Rules. (D.I. 104.) Defendants determined in October 2013 that it was not necessary to reopen claim construction. Defendants have offered no substantive reason for why their manufactured third-party discovery dispute should *now* throw the parties' completed briefing into disarray by permitting new constructions to be introduced. In addition to rendering obsolete any work done by the Court concerning the proper construction of the disputed terms, any new supplemental claim construction briefing will require the parties to file new declarations, file new briefs, and take new depositions. Plaintiffs have already suffered severe financial penalty and uncertainty based on the reset of this case caused by Defendants' failure to disclose their revised ANDA and its new assignees. Further delay in the prosecution of this case is simply unwarranted.

C. There Is No Basis To Preclude Plaintiffs' Contentions Concerning Secondary Considerations Of Nonobviousness

In the Motion, Defendants argue that:

Plaintiffs failed to provide any substantive response to this request until after the close of business on the last day of discovery, when they identified their theories of secondary considerations and supporting documents for the first time. As a result, Defendants were unable to pursue any meaningful fact discovery into the highly factual assertions of secondary considerations.

(Motion at 26.) That argument conflicts squarely with the record, the law and common sense for at least three reasons.

First -- and contrary to Defendants' suggestions -- Plaintiffs provided significant discovery relevant to the secondary considerations of nonobviousness well before the fact discovery deadline. Moreover, Plaintiffs supplemented their interrogatories in a timely fashion.⁶ The record is undisputed that Plaintiffs served their supplemental interrogatory responses prior to the close of fact discovery in

⁶ Defendants and their counsel fixate on the fact that Plaintiffs supplemented their interrogatories after the "close of business". (*See, e.g.*, D.I. D.I. 329 at 32.) ("And we never got any discussion of secondary considerations ***until 8:00 o'clock at night*** on October 31st of 2013 when the fact discovery was closed.") That fact is, however, immaterial. Plaintiffs' supplements were in the process of being prepared and were, in fact, served before the end of fact discovery. Moreover, interrogatories were not the only discovery vehicle through which relevant information on secondary considerations was provided. Plaintiffs also produced responsive documents.

compliance with the Scheduling Order and Plaintiffs' obligations under the Federal Rules. FED. R. CIV. P. 26(e). Defendants do not cite a single case to support their sweeping assertions that Plaintiffs' supplementation of their interrogatory responses was untimely or improper in any way. Defendants also fail to describe in their Motion the fact discovery they would have sought and did not otherwise obtain.⁷ This is not surprising because, as set forth below, evidence of secondary considerations is typically the subject of expert discovery.

Second, Defendants could not have been surprised by Plaintiffs' actions or the lack of a "substantive response" prior to the close of fact discovery. Plaintiffs advised Defendants in writing that they would supplement their interrogatory responses "as soon as possible, and certainly before the close of fact discovery". (D.I. 240-7 at 3.) Plaintiffs prepared those supplemental interrogatory responses in the final weeks of fact discovery, during which the parties scheduled nineteen party and third-party depositions. As Plaintiffs told Defendants, Plaintiffs sought to complete those depositions before supplementing their interrogatory responses.

Third, conclusions concerning how a person having ordinary skill in the art would assess the secondary considerations of nonobviousness are not typically

⁷ And, of course, having failed to do so in their opening brief, Defendants should not be permitted to ambush Plaintiffs by revealing that critical argument in their reply brief.

addressed during fact discovery. Defendants either do not understand, or otherwise ignore, this practice. During oral argument on Defendants' motion to compel, Defendants argued:

Now, they are going to come back and say, well, that is an expert discovery matter. It is not. Experts take facts, synthesize them, and come up with a report. What we wanted was, what are the facts here? What has Bayer sold out of this product? You know, what -- who told you there was a long-felt commercial need for this product? We have just been cut off from doing any discovery into that at all.

(D.I. 329 at 32.) There are significant flaws with Defendants' argument.

As an initial matter, and contrary to Defendants' suggestion, Plaintiffs provided facts relevant to the issue of secondary considerations in their document production and in the timely supplemental responses to Defendants' Interrogatory No. 5. Those supplemental responses identified by production number certain documents relevant to Plaintiffs' arguments. (Exs. 3 and 4.) Defendants were so uninterested in the issue of secondary considerations that they failed to inquire about that topic of any witness during fact discovery, or to seek party deposition topics under Rule 30(b)(6) on facts potentially relevant to those considerations (*e.g.*, by seeking a party witness to testify concerning financial statements).⁸

⁸ The ultimate conclusion of a patent's validity is a legal determination based upon those facts. *See, e.g., KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 427

Beyond that, as Plaintiffs made clear in their objections to Defendants' Interrogatory No. 5, secondary considerations of nonobviousness are properly addressed during *expert* discovery, not fact discovery. (Ex. 3 at 6; Ex. 4 at 6.) This is because the obviousness determination requires insight from experts. *See, e.g., Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1295-1299 (Fed. Cir. 2012) (remanding the question of obviousness to the district court for redetermination with the inclusion of expert testimony regarding secondary considerations); *id.* at 1299 ("Although Union Rich asks this court to decide the question of nonobviousness on our own, the exclusion of the expert's testimony leaves us with no better basis for decision than was available to the trial court."); *see also Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966) (noting that the "obviousness or nonobviousness of the subject matter is determined" against a background of "the level of ordinary skill in the pertinent art").

Consistent with this practice, Plaintiffs served two expert reports directed to secondary considerations of nonobviousness. For their own unstated reasons, however, Defendants did not retain their own experts to address these issues. Defendants had ample opportunity to review Plaintiffs' experts' reports and take

(2007). Plaintiffs, accordingly, asserted an objection in response to Defendants' Interrogatory No. 5 as seeking a legal conclusion. (Ex. 3 at 6; Ex. 4 at 6.)

Plaintiffs' experts' depositions. Defendants decided to take only one of those two depositions and, despite Plaintiffs' offers, did not reschedule the second.⁹

Plaintiffs' disclosure of secondary considerations is fully consistent with this Court's Scheduling Order. Defendants bear the burden of proving invalidity in this case; patents are presumed valid. 35 U.S.C. § 282. Accordingly, Defendants' opening expert reports addressed their alleged invalidity arguments. Plaintiffs then responded to Defendants' arguments in the second round of reports and also offered opinions concerning secondary considerations of nonobviousness, which rebut Defendants' arguments. Finally, in the third round of reports, Defendants' experts *could* have provided responsive arguments concerning secondary considerations. But Defendants chose to ignore Plaintiffs' arguments and did not have any of their experts opine on that issue. Whether through indifference or inattention, Defendants' failures are not a reason to substantively sanction Plaintiffs.

Defendants' lack of any real interest in pursuing fact or expert discovery about secondary considerations reveals Defendants' true motive: to derail Plaintiffs' secondary considerations arguments using a trumped-up discovery dispute, because they cannot compete on the law or the facts.

⁹ One of Plaintiffs' experts needed to reschedule the original deposition date due to a family emergency.

III. CONCLUSION

For the foregoing reasons, Defendants' Motion should be denied.

Dated: April 18, 2014

Respectfully submitted,

MORRIS, MANNING & MARTIN, LLP

By: /s/ Bryan G. Harrison

Bryan G. Harrison

bgh@mmmlaw.com

Georgia Bar No. 331750

W. Andrew McNeil

wmcneil@mmmlaw.com

Georgia Bar No. 498636

1600 Atlanta Financial Center

3343 Peachtree Road, N.E.

Atlanta, Georgia 30326

Phone: (404) 233-7000

Fax: (404) 365-9532

OF COUNSEL:

ROPES & GRAY LLP

Bradford J. Badke

jim.badke@ropesgray.com

Michael P. Kahn

michael.kahn@ropesgray.com

1211 Avenue of the Americas

New York, NY 10036

Phone: (212) 596-9000

Fax: (212) 596-9090

*Attorneys for Plaintiffs Bayer HealthCare
Pharmaceuticals Inc. and Dow
Pharmaceutical Sciences, Inc.*

LOCAL RULE 5.1 CERTIFICATION

I certify that this document was prepared using Times New Roman (14 point) font pursuant to Local Rule 5.1.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system this 18th day of April, 2014.

DATED: April 18, 2014

/s/ Bryan G. Harrison

Bryan G. Harrison

Georgia Bar No. 331750